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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,638	08/19/2003	Howard R. Levin	3659-70	3724
23117	7590	06/15/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 06/15/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,638	LEVIN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-71 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 55-71 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 55-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,211,850 to Shettigar et al in view of US 4,861,485 to Fecondini. Shettigar discloses a blood filter that removes blood from a patient, runs it through a filter, and returns filtered blood to the patient. The internal surface area of the filter may be between 0.1 and 5.0 m², the length of the fibers may be 20-25 cm², and the flow rate of the blood through the filter may be 50-3000 mL/min. With regard to the diameter of the fiber bundle, Shettigar discloses that the preferred embodiment of the device has a fiber length of 20cm, and illustrates an embodiment that shows the diameter of the fiber bundle to be less than 1/13th of the length of the fibers, indicating that the diameter of the bundle is less than 1.5cm. Shettigar discloses the claimed apparatus as explained above, but does not disclose the number of fibers, or the shear rate of the blood flow therethrough. However, Shettigar discloses that the filter dimensions, flow rate, blood shear rate, and transmembrane pressure are all interrelated in the art of blood filtration. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adjust the dimensions, flow rate, and shear rate of the procedure and device via manipulation of the transmembrane pressure in order to effectively filter the

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blood according to the desired outcome. Furthermore, Shettigar fails to disclose that the hollow fibers block passage of molecules larger than 50,000 Daltons and a straight filter. Fecondini discloses a straight hollow-fiber filter wherein one of the membranes has a molecular weight cutoff of 30,000-50,000 Daltons, thereby preventing larger molecules, such as albumin, from passing through the fibers. Furthermore, the fibers are arranged in a straight housing to provide efficient countercurrent exchange between the blood and diasylate in the filter. After traveling through the filter device, the blood wastes and blood plasma water (loss of blood plasma water results in a concentration of the blood) are passed out of the diasylate outlet. The passage is controlled by means of pressure regulation, which may comprise a pump. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the Shettigar device by using a smaller pore size in the membrane to prevent albumin transfer, constructing the filter in a straight shape to provide for more efficient exchange, and removing the blood and plasma water as waste, as taught by Fecondini.

3. In the alternative, claims 55-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over a disclosure of the Hospal Miniflow 10 (see pages of internet data, accompanied by 1997 study from Gouyon et al, showing the existence of the Miniflow 10 as early as 1997). The Miniflow is disclosed and shown as having a hollow fiber surface area below 0.1m², appears to be at least 20cm long and less than 1.5cm in diameter, an input and an output line. The Miniflow documentation does not disclose the molecular weight of the molecules filtered, but Fecondini discloses an ultrafilter with molecular weight specifications. Fecondini discloses a straight hollow-fiber filter wherein

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one of the membranes has a molecular weight cutoff of 30,000-50,000 Daltons, thereby preventing larger molecules, such as albumin, from passing through the fibers.

Furthermore, the fibers are arranged in a straight housing to provide efficient countercurrent exchange between the blood and diasylate in the filter. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the Miniflow device by using a smaller pore size in the membrane to prevent albumin transfer as taught by Fecondini.

Response to Arguments

4. Applicant's arguments filed 14 March 2005 have been fully considered but they are not persuasive. Applicant argues that the Shettigar device is not suitable for ultrafiltration. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., performance of ultrafiltration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant merely claims a filtration operation, not an ultrafiltration operation, which is a term of art and serves to distinguish one method of filtration from another. Applicant's arguments are narrower than the method actually claimed in the instant application.

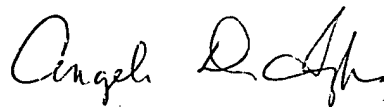
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
6 June 2005



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700